

NL

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
29 November 2001 (29.11.2001)

PCT

(10) International Publication Number
WO 01/89431 A1

(51) International Patent Classification⁷: **A61F 5/00**

(21) International Application Number: PCT/US01/15611

(22) International Filing Date: 15 May 2001 (15.05.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/206,226 22 May 2000 (22.05.2000) US

(71) Applicant and

(72) Inventor: **COFFEY, Arthur, C.** [US/US]; 12530 Glendurgan Drive, Carmel, IN 46032 (US).

(74) Agent: **COFFEY, William, R.**; Barnes & Thornburg, 11 South Meridian Street, Indianapolis, IN 46204 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

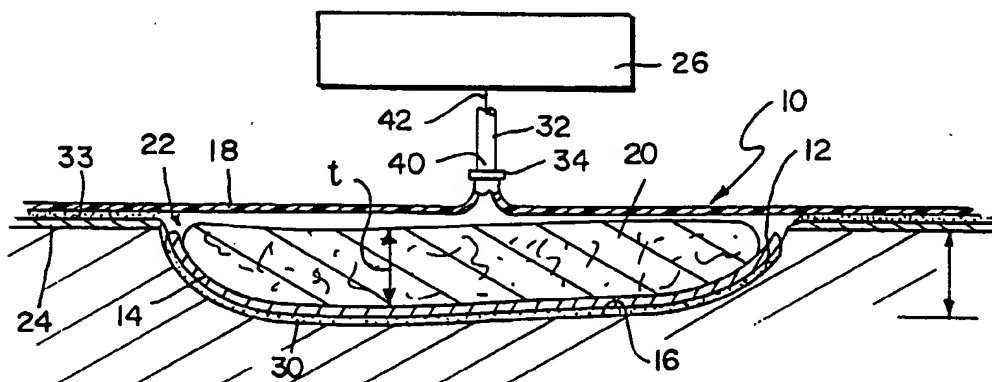
— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG)

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMBINATION SIS AND VACUUM BANDAGE AND METHOD



(57) Abstract: A wound care bandage (10) for treating a wound (12) is provided. The bandage (10) includes an SIS layer (14) to be placed on the wound surface (16) and a cover (18) to be placed over the wound (12). The bandage (10) further includes a structure (20) to provide a vacuum space (22). A method for promoting wound healing is further provided. The method includes applying the above-mentioned wound care bandage (10) to the wound (12) and creating a vacuum in the vacuum space (22) to draw blood controllably from the wound (12) into the SIS layer (14).

WO 01/89431 A1

-1-

COMBINATION SIS AND VACUUM BANDAGE AND METHODBackground of the Invention

The present invention relates to wound care and more particularly to
5 the provision of an SIS wound care cover used in combination with a vacuum
bandage. The invention contemplates both apparatus and a method for using the
apparatus.

It is known to use small intestine submucosa (SIS) in wound care
treatment, particularly the application of layers of SIS directly upon an open wound
10 that has been debrided and cleaned. SIS is described in the following U.S. Patents:
5,855,619, 5,866,414, 5,753,267, 5,762,966, 5,755,791, 4,902,508, 4,956,178,
5,275,826, 5,281,422, 4,352,463, 5,372,821, 5,445,833, 5,516,533, 5,573,784,
5,645,860, 5,641,518, 5,711,969, and 5,695,998. These patents disclose the nature of
SIS.

15 SIS has been described as a natural acellular biomaterial used to repair,
support, and stabilize a wide variety of anatomical defects and traumatic injuries.
See, for example, Cook® Online New Release provided by Cook Biotech at
“www.cookgroup.com”. The SIS material is a tissue engineered collagen matrix
derived from porcine small intestinal submucosa that models the qualities of its host
20 when implanted in human soft tissues. Further, it is taught that the SIS material
provides a natural scaffold-like matrix with a three-dimensional structure and
biochemical composition that attracts host cells and supports tissue remodeling.
Surgisis™ Soft Tissue Repair Biomaterial and Oasis™ Wound Dressing Biomaterial
are available for remodeling partial thickness skin injuries (Cook Biotech,
25 Bloomington, IN). The Oasis™ Wound Dressing is provided in single thickness,
fenestrated sheets. It will be appreciated that SIS is readily available for use as a
wound dressing.

While small intestine submucosa is available, other sources of
submucosa are known to be effective for tissue remodeling. These sources include,
30 but are not limited to, stomach, bladder, alimentary, respiratory, or genital submucosa.
See, e.g., U.S. Patents Nos. 6,171,344, 6,099,567, and 5,554,389. Further, it is known
that these various submucosa materials may be derived from non-porcine sources,

-2-

including bovine and ovine sources. Additionally, other collagen matrices are known, for example lamina propria and stratum compactum.

It is also known to use a vacuum treatment bandage for accelerating wound healing. A vacuum bandage is a bandage having a cover for sealing about the outer perimeter of the wound and under which a vacuum is established to act on the wound surface. This vacuum applied to the wound surface accelerates healing of chronic wounds. Typically, suction tubes are provided for drawing exudate away from the wound, and the suction tubes may be used to create the vacuum under the cover. If the cover is a flexible cover, which is typically more comfortable for the patient, a porous packing may be provided under the cover to provide the space in which the vacuum is formed. Additionally, it is known a heater within a wound treatment apparatus to promote healing. The following U.S. Patents establish the nature of vacuum and/or heat treatment bandages and devices: 6,095,992, 6,080,189, 6,071,304, 5,645,081, 5,636,643, 5,358,494, 5,298,015, 4,969,880, 4,655,754, 4,569,674, 4,382,441, and 4,112,947.

As shown, for example, in U.S. Patent No. 5,645,081 (hereinafter the '081 patent), a method of treating tissue damage is provided by applying negative pressure to a wound. The negative pressure is provided in sufficient duration and magnitude to promote tissue migration in order to facilitate the closure of the wound. Fig. 1 of the '081 patent discloses an open cell polyester foam section covering the wound, a flexible hollow tube inserted into the foam section at one end and attached to a vacuum pump at another end, an adhesive sheet overlying the foam section, and tubing to adhere to the skin surrounding the wound in order to form a seal that allows the creation of a vacuum when the suction pump is operating. The '081 patent further teaches use of negative pressure between about 0.1 and 0.99 atmospheres, and that the pressure can be substantially continuous, wherein the pressure is relieved only to change the dressing on the wound. Alternatively, the '081 patent teaches use of a cyclic application of pressure in alternating periods of application and non-application. In a preferred embodiment, pressure is applied in 5 minute periods of application and non-application.

The following pending applications, assigned to the same assignee as the present application is licensed, are also related to the use of vacuum to promote

-3-

healing: U.S. Patent Application Serial No. 09/369,113 filed August 5, 1999, and titled Wound Treatment Apparatus, U.S. Patent Application Serial No. 09/725,352 filed November 29, 2000, and titled Vacuum Therapy and Cleansing Dressing for Wounds, and U.S. Patent Application Serial No. 09/725,666 filed November 29, 5 2000, and titled Wound Treatment Apparatus.

Various of prior art references teach the value of the vacuum bandage or the provision of vacuum to the surface of a chronic wound. Several Russian language articles exist that establish the efficacy of vacuum therapy. Examples of such prior art articles, each of which discusses the use of application of vacuum to a 10 wound to promote healing, are as follows: Vacuum therapy in the treatment of acute suppurative diseases of soft tissues and suppurative wound, Davydov, et al. Vestn. Khir., Sept. 1988 ("the Sept. 1988 article"); Pathenogenic mechanism of the effect of vacuum therapy on the course of the wound process, Davydov, et al. Khirurgiia, June 1990 ("the June 1990 article"); and Vacuum therapy in the treatment of suppurative 15 lactation mastitis, Davydov, et al., Vestn. Khir., Nov. 1986 ("the Nov. 1986 article").

The Russian articles distinguish wound drainage from use of vacuum therapy for healing, and they report that vacuum therapy results in faster cleansing of the wound and more rapid detoxification than with the traditional incision-drainage method. The Nov. 1986 article describes the vacuum therapy protocol as 0.8 - 1.0 20 atmosphere for 20 minutes at the time of surgery, and subsequent 1.5 to 3 hour treatments at a vacuum of 0.1 to 0.15 atmosphere, twice daily. These Russian articles teach that use of negative pressure accelerates healing. The Russian articles further teach using this vacuum method to decrease the number of microbes in the wound. The June 1990 article teaches that vacuum therapy provides a significant antibacterial 25 effect. The June 1990 article describes the stepped up inflow of blood to the zone around the wound, which leads to an increase in the number of leukocytes reaching the focus of inflammation. Moreover, the Russian articles teach improvement of local blood circulation using vacuum therapy. The September 1988 article teaches improved inflow of blood into the wound zone, which intensifies the repair processes. 30 The June 1990 article teaches that vacuum therapy promotes mobilization of blood plasma, intertissue fluid, and lymph into the wound. The June 1990 article reports that cellular and non-cellular elements of connective tissue appear twice as quickly in

-4-

wounds treated with vacuum therapy. Subsequent articles and patents further develop the benefits obtained with vacuum therapy. The prior art, therefore, teaches the benefit and value of a vacuum bandage.

5 Summary of the Invention

According to the present invention, a wound care bandage is provided that combines the advantages of SIS and vacuum therapy to control and enhance the flow of fluid from the wound bed and into the SIS material. The present invention, therefore, is a method for controllably drawing fluid from the surrounding tissue and
10 into an SIS layer placed on the wound, thereby enhancing the healing and restructuring properties of the SIS.

The present invention comprises structure to provide a space above the SIS and the wound bed, in which space a vacuum is developed to cause blood flow from the wound bed into the SIS. Furthermore, the method contemplates controlling
15 the vacuum level and the application time of the vacuum to present optimum blood flow from the wound bed into the SIS.

In preferred embodiments, the wound care bandage includes an SIS layer to be placed in contact with the wound bed. As mentioned above, the wound care bandage further includes a structure placed over the SIS layer to provide a
20 vacuum space between the SIS layer and a cover placed over the structure and SIS layer. The cover is coupled to the patient's skin surrounding the wound to provide a sealed environment. A vacuum source is coupled to the wound covering for communication with the vacuum space created by the structure. The vacuum source is used to create a vacuum within the sealed environment in order to draw blood from
25 the wound bed up through the SIS layer to promote the healing process. The vacuum suction is to be at a level sufficient to draw blood to the SIS layer, for example, 125 mm Hg. It will be appreciated, however, that varying levels of vacuum suction and varying protocols for the duration of application of vacuum are within the scope of the present invention.

30 In further embodiments, the space-providing structure is a porous or reticulated pad or other structure having air passageways extending from the SIS layer

-5-

to the cover. In still further embodiments, the space-providing structure may be a foam ring, or it may be the cover itself, provided that the cover is sufficiently rigid.

Thus, in one aspect of this invention a wound care bandage is provided comprising a collagen matrix formed for placement on a wound, a cover configured
5 for placement over the wound to provide a sealed environment around the wound and adapted for communication with a vacuum source, and a structure for placement between the collagen matrix and the cover and configured to provide a vacuum space. In preferred embodiments, the collagen matrix is a layer of submucosa.

In another aspect of this invention a wound care bandage is provided
10 comprising an SIS layer adapted to be placed on a wound, and a cover configured to be placed over the wound and the SIS layer to provide a vacuum space between the SIS layer and an inside surface of the cover, the space being connectable with a vacuum source.

Still another aspect of this invention includes a method for promoting
15 wound healing comprising the steps of providing a wound care bandage having an SIS layer adapted to be placed on a wound, a cover to be placed over the wound to provide a vacuum space above the wound, a structure to define the vacuum space between the SIS layer and the cover, and creating a vacuum within the vacuum space to controllably draw blood from the wound into the SIS layer placed over the wound.

Yet another aspect of this invention is directed to a method for
20 promoting wound healing comprising the steps of applying an SIS layer to a wound surface, placing a support structure over the SIS layer, placing a cover over the wound, SIS layer and support structure to define a vacuum space, connecting the cover to a vacuum source, and creating a vacuum within the vacuum space.

An additional aspect of this invention is directed to a method for
25 promoting wound healing comprising the steps of applying a collagen matrix to a wound surface, creating a vacuum space in communication with the wound and the collagen matrix, and generating a vacuum within the vacuum space in a magnitude and duration sufficient to draw blood from the wound into the collagen matrix.

A final aspect of this invention is a kit for promoting wound healing,
30 the kit comprising a submucosa layer for contacting the wound, a porous pad, and

-6-

a cover for creating a seal around the wound and configured for communication with a vacuum source.

Brief Description of the Drawings

5 The detailed description particularly refers to the accompanying figures in which:

Fig. 1 is a sectional view of a debrided wound and a wound care bandage showing an SIS layer, a porous pad or filler, and a cover of the wound care bandage, and further showing the cover of the wound care bandage in communication
10 with a tube adapted to lead to a vacuum source;

Fig. 2 is a plan view of the SIS layer shown in Fig. 1 showing fenestrations in the SIS layer;

Fig. 3 is a sectional view of another debrided wound and another wound care bandage including an SIS layer, a walled structure to provide a vacuum space, a covering, and a vacuum tube positioned to lie under the cover and in
15 communication with the vacuum space at one end and a vacuum source at another end;

Fig. 4 is a sectional view of another embodiment of the present invention showing another wound care bandage over a debrided wound and showing
20 the bandage including an SIS layer, a ring-shaped structure defining a vacuum space in communication with the vacuum source, and a cover positioned over the structure; and

Fig. 5 is a sectional view of another embodiment of the present invention showing the bandage including a semi-rigid walled structure for defining a
25 vacuum space in communication with the vacuum source.

Detailed Description of the Drawings

A wound care bandage 10 is provided, as shown in Figs. 1-5, for use with a debrided wound 12. Referring to Fig. 1, bandage 10 includes a small intestinal submucosa (SIS) layer 14 which lies adjacent to a wound surface 16 of wound 12.
30 Bandage 10 further includes a cover 18 for placement over wound 12 and a structure 20, 120, 220, or 320 positioned between SIS layer 14 and cover 18 in order to create a

-7-

vacuum space 22. Cover 18 is coupled to a portion of the patient's skin 24 surrounding wound 12 in order to enclose wound 12, SIS layer 14, and structure 20, 120, 220, or 320 within a sealed environment. Bandage 10 further includes a means for communicating vacuum space 22 with a vacuum source 26. The wound care
5 bandage 10, therefore, combines the healing properties of the SIS layer 14 with the acceleration provided by the vacuum therapy.

SIS layer 14, which is applied directly to wound surface 16, may be fenestrated (or perforated) to prevent fluid accumulation below the SIS layer 14. Such fenestrations 28 are shown, for example, in Fig. 2. Equipment is available for
10 fenestrating skin grafts and it is contemplated that such equipment could also be used to fenestrate SIS layer 14. These fenestrations 28, or perforations, in the SIS layer 14 permit blood from the wound 12 to migrate upwardly into the SIS layer 14 and deposit cells to start the tissue growth in the SIS framework of the SIS layer 14.

Further, SIS layer 14 may be formed to include one single sheet of SIS
15 or multiple sheets of SIS. For SIS layer 14 including multiple SIS sheets, the sheets may be positioned in any number of orientations relative to each other. It is further within the scope of the disclosure for SIS layer 14 to have any reasonable thickness for its use in bandage 10. It is also known in the art that larger sheets of submucosa may be formed by fusing multiple strips of submucosa tissue. See U.S. Patent No.
20 5,711,969. In a preferred embodiment, SIS layer 14 is sized to fit the wound and is flexible in order to allow the SIS layer 14 to conform to any complex wound or wound surface. Additionally, it is known to treat wounds with SIS provided in fresh, frozen, or lyophilized forms. Lyophilized SIS may be used in the dried form, or it may be hydrated prior to use.

25 In some optional embodiments, a biological glue 30 is provided between the debrided wound surface 16 and the SIS layer 14 in order to hold the SIS layer 14 in a stationary position against the wound surface 16, as shown, for example, in Fig. 1. One type of biological glue 30 used may be a fibrin sealant, for example. It is within the scope of this disclosure, however, to include any type of biological glue
30 sufficient for holding the SIS layer 14 stationary relative to wound surface 16.

SIS is intended to identify porcine small intestine submucosa. While reference is made herein to SIS, it will be appreciated that small intestine submucosa

-8-

may be obtained from other animal sources, including cattle, sheep, and other warm-blooded mammals. Further, other sources of submucosa from various tissue are known to be effective for tissue remodeling as well. These sources include, but are not limited to, stomach, bladder, alimentary, respiratory, and genital submucosa.

5 Such submucosa-derived matrices comprise highly conserved collagens, glycoproteins, proteoglycans, and glycosaminoglycans. Additionally, other collagen matrices are known that can act as a biological scaffolds. Thus, it is understood that while the preferred embodiment uses SIS, other collagen matrices may be used within the scope of this invention.

10 The structure of bandage 10, is provided to form vacuum space 22 between SIS layer 14 and cover 18. A structure supports cover 18 while providing air passageways to the wound surface 16 and the SIS layer 14. As shown in Fig. 1, the structure is preferably a reticulated or porous filler or pad 20 having airflow passageways (not shown) extending throughout pad 20. It is preferred that pad 20 be
15 rather flexible to conform to any complex wound or wound surface and to be comfortable for the patient. Further, it is preferred that the thickness of the structure is selected to provide proper vacuum access to all parts of the wound to be served. It is further preferred that a thickness, t , of the reticulated flexible pad 20 be approximately one to two centimeters. The reticulated or porous pad 20 may be cut
20 by the surgeon to be larger than the SIS layer 14 and even larger than the wound 12.

Although porous pad 20 has been described above, it is within the scope of this disclosure to include any such structure which functions to create a space between the SIS layer 14 and the cover 18 and permits air flow from the wound 12 to transmit negative pressure to the wound surface 16. As shown in Fig 3, the structure
25 120 may be gauze, or, as shown in Fig. 4, the structure may be a foam ring 220 or other such ring to position cover 18 in spaced-apart relation to SIS layer 14. Ring 220 includes an aperture defined by an inner wall 221 of the ring 220. The vacuum space 22 is thus defined by the SIS layer 14, the cover 18, and the inner wall 221 of ring 220.

30 Further, as shown in Fig. 5, for example, the structure may be a rigid dome or a preferably semi-rigid dome 320 which supports the cover 18 above the SIS layer 14. Semi-rigid dome 320 includes a lower member 322 adapted to lie adjacent

-9-

the patient's skin surrounding wound 12, an upper member 324 normally spaced-apart from SIS layer 14, and a middle member 326 for supporting the upper member 324 in spaced-apart relationship with the SIS layer 14. Semi-rigid dome 320 may be generally dome-shaped, for example, as well. Although such examples as porous pad 20, foam ring 220, and semi-rigid dome 320 have been provided as examples for the structure, it is within the scope of this disclosure for bandage 10 to include any space providing structure above the SIS layer 14 and below the cover 18 for communication with a vacuum service 26.

Cover 18 of the bandage 10 lies over the space-providing structure to fully enclose the structure, SIS layer 14, and wound 12. Cover 18 is coupled to the patient's skin 24 which surrounds the wound 12. For example, cover 18 may be a thin transparent, non-porous adhesive sheet to adhere to the surface of the skin 24 about the wound 12 to provide a vacuum enclosure. An adhesive 33 for coupling cover 18 to skin 24 is shown in Figs. 1 and 3-5. A product such as Tegaderm™ (3M Health Care Ltd., (St. Paul, MN)) would be suitable for the cover, for example. It is within the scope of this disclosure, however, to include any suitable non-porous impermeable or semi-permeable sheet. While a flexible or semi-rigid sheet is preferred for patient comfort, a rigid cover, such as a glass dome, is within the scope of this invention. When a rigid cover is used, a separate space-providing structure is not needed, as the rigid cover may be configured to provide the vacuum space.

In order to encourage blood flow to the wound 12 and wound surface 16, vacuum space 22 of wound care bandage 10 is connected with vacuum source 26. A vacuum tube 32 may be provided, for example, for fluid communication with vacuum space 22 and vacuum source 26. As shown in Fig. 1, vacuum tube 32 is coupled to cover 18 and in communication with vacuum space 22. A first end 40 of tube 32 includes a collar 34 coupled to an aperture of the cover 18. As shown diagrammatically, a second end 42 of tube 32 is coupled to vacuum source 26.

In other embodiments, as shown in Figs. 3-5, for example, tube 32 is placed under cover 18 and into vacuum space 22. Cover 18 is sealed around tube 32 in order create a sealed environment for the vacuum to function properly. The vacuum may be provided by a suction tube disposed in the space and configured to draw excess wound drainage away from the wound. Another type of fluid connection

-10-

system between a wound dressing and a vacuum source is disclosed in U.S. Patent No. 4,969,880. Furthermore, while first end 40 of tube 32 is shown in Figs. 3 and 4 as being located in the structure 120 or 220, it is understood that first end 32 may be placed directly on the SIS layer 14. Additionally, it is understood that tube 32 may be
5 a Jackson-Pratt type drain, with holes distributed along its length adjacent first end 32.

The vacuum may be provided in vacuum space 22 for controlled periods of time. For example, initially, the vacuum may be applied for a sufficient time to draw blood into the SIS layer 14, such as up to 125 mm Hg, for example. It will be appreciated that this invention contemplates developing different protocols for
10 amounts of vacuum and application times. It will also be appreciated that the vacuum may be provided by a perforated tube positioned and configured to carry away excess wound drainage.

In treating wound 12, a caretaker first cleans and prepares the wound surface 16. Once wound surface 16 is prepared, bandage 10 is to be applied to the
15 wound. SIS layer 14 is positioned over the wound 12 to cover the prepared wound surface 16. Structure 20, 120, 220, or 320 is placed over the SIS layer 14 to define the vacuum space and cover 18 is placed over the wound 12, SIS layer 14, and structure 20. Cover 18 is connected to a vacuum source 26. Finally, suction is applied to the vacuum space 22 in sufficient magnitude and duration to draw blood from the wound
20 into the SIS layer 14. Optionally, a biological glue 30 may be placed on the wound surface 16 prior to application of the bandage 10.

Vacuum may be applied at any magnitude or duration to promote inflow of blood from the wound into the layer of SIS. Preferably, vacuum may be applied from 0.1 to 0.99 atmospheres, and more preferably 0.1 to 0.15 atmospheres.
25 In one embodiment, vacuum is applied essentially continuously until healing takes place. In another embodiment, vacuum is used in periods of application and non-application, and the structure and cover may be removed during periods of non-application. These alternating periods may include one or two periods of application each day for several days. In another embodiment, the negative pressure is applied in
30 5 minute periods of application and non-application.

It is known that SIS can be integrated into the wound and restructured to resemble the surrounding tissue. Thus, while the magnitude and duration of

-11-

application of vacuum may vary, in a preferred embodiment the SIS remains on the surface of the wound for the duration of treatment. In optional embodiments, additional layers of SIS may be added as the SIS is integrated into the wound. The additional layers may be smaller pieces to be placed on localized areas of integration, or, because the vacuum promotes blood flow into the SIS layer, may be full size pieces conforming to the size of the wound surface.

Thus, in one embodiment the present invention is a method for treating wounds comprising the steps of preparing the wound surface, applying a bandage to the wound, the bandage having an SIS layer secured over the wound and a cover above the wound and the SIS layer to define a vacuum space between the wound and SIS layer, and applying suction to the vacuum space to draw blood from the wound into the SIS layer.

Although this invention has been described in detail with reference to certain embodiments, variations and modifications exist within the scope and spirit of the invention as described and defined in the following claims.

-12-

CLAIMS:

1. A wound care bandage comprising:
a collagen matrix formed for placement on a wound,
5 a cover configured for placement over the wound to provide a sealed environment around the wound and adapted for communication with a vacuum source, and
a structure for placement between the collagen matrix and the cover and configured to provide a vacuum space.
- 10 2. The bandage of claim 1, wherein the collagen matrix comprises a submucosa layer.
- 3 The bandage of claim 2, wherein the submucosa layer is an SIS layer.
- 4 The bandage of claim 3, wherein the SIS layer includes one or
15 more sheets of SIS.
- 5 The bandage of claim 3, wherein the SIS layer is fenestrated.
- 6 The bandage of claim 1, wherein the bandage further includes a biological glue for positioning between the wound and the collagen matrix for holding the collagen matrix stationary relative to the wound.
- 20 7. The bandage of claim 6, wherein the glue is a fibrin sealant.
- 8 The bandage of claim 1, wherein the cover includes a first surface and a second surface and the first surface includes an adhesive for adhering to skin adjacent the wound.
- 9 The bandage of claim 8, wherein the cover further includes a
25 port adapted to communicate with the vacuum source.
- 10 The bandage of claim 3, wherein the structure is a porous pad including air passageways between the cover and the SIS layer to define the vacuum space.
- 11 The bandage of claim 10, wherein the pad is adapted to be cut
30 to fit the wound.
- 12 The bandage of claim 10, wherein the pad comprises a flexible material.

-13-

13. The bandage of claim 10, wherein the pad has a thickness of approximately 1-2 centimeters.

14. The bandage of claim 1, wherein the structure is a ring having an aperture defined by an inner wall of the ring and wherein the vacuum space is defined by the collagen matrix, the cover, and the inner wall of the ring.

15. The bandage of claim 1, wherein the structure is a semi-rigid wall configured to lie spaced-apart from the collagen matrix and adjacent to the cover.

16. The bandage of claim 15, wherein the semi-rigid wall includes a lower member adapted to lie adjacent a patient's skin surrounding the wound, an upper member configured to remain in a spaced-apart relationship from the SIS layer, and a middle member integrally coupled to the upper and lower members, the middle member provided to support the upper member in the spaced-apart relationship with the SIS layer.

17. The bandage of claim 15, wherein the semi-rigid wall is dome-shaped.

18. The bandage of claim 1, further comprising tubing for connecting the cover to the vacuum source.

19. A wound care bandage comprising:
an SIS layer adapted to be placed on a wound, and
a cover configured to be placed over the wound and the SIS layer to provide a vacuum space between the SIS layer and an inside surface of the cover, the space being connectable to a vacuum source.

20. The bandage of claim 19, further comprising a vacuum tube for connecting the cover to the vacuum source.

21. A method for promoting wound healing comprising the steps of:

providing a wound care bandage having an SIS layer adapted to be placed on a wound, a cover to be placed over the wound to provide a vacuum space above the wound, and

creating a vacuum within the vacuum space to controllably draw blood from the wound into the SIS layer placed over the wound.

-14-

22. The method of claim 21, wherein the vacuum is applied at intervals of application and non-application to controllably draw fluid from the wound into the SIS layer.

23. The method of claim 21, wherein the vacuum source is applied
5 at a constant rate to controllably draw blood from the wound into the SIS layer.

24. The method of claim 21, wherein the creating step includes creating a vacuum of about 0.1 to about 0.15 atmospheres.

25. The method of claim 21, further comprising a structure positioned to define the vacuum space between the SIS layer and the cover.

10 26. A method for promoting wound healing comprising the steps of:

applying an SIS layer to a wound surface,

placing a support structure over the SIS layer,

placing a cover over the wound, SIS layer and support structure to

15 define a vacuum space,

connecting the cover to a vacuum source, and

creating a vacuum within the vacuum space.

27. A method for promoting wound healing comprising the steps of:

20 applying a first collagen matrix to a wound surface,

creating a vacuum space in communication with the wound and the first collagen matrix, and

generating a vacuum within the vacuum space in a magnitude and duration sufficient to draw blood from the wound into the first collagen matrix.

25 28. The method of claim 27, wherein the first collagen matrix comprises a submucosa layer.

29. The method of claim 28, wherein the submucosa layer is an SIS layer.

30 30. The method of claim 27, wherein the creating step includes positioning a structure between the first collagen matrix and the cover to provide the vacuum space.

-15-

31. The method of claim 30, wherein the structure is a porous pad including air passageways between the cover and the first collagen matrix to define the vacuum space.

32. The method of claim 30, wherein the structure is a ring having an aperture defined by an inner wall of the ring and wherein the vacuum space is defined by the first collagen matrix, the cover, and the inner wall of the ring.

33. The method of claim 30, wherein the structure is a semi-rigid wall configured to lie spaced-apart from the first collagen matrix and adjacent to the cover.

10 34. The method of claim 27 wherein the vacuum is provided in periods of application and non-application.

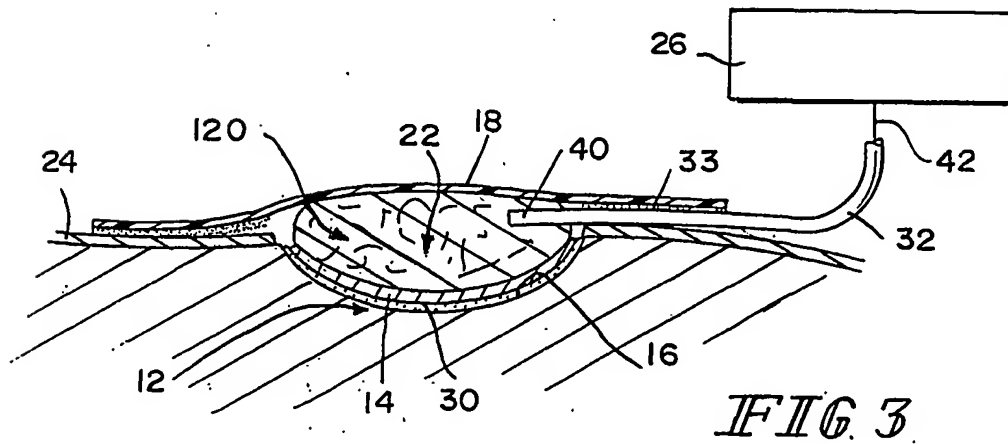
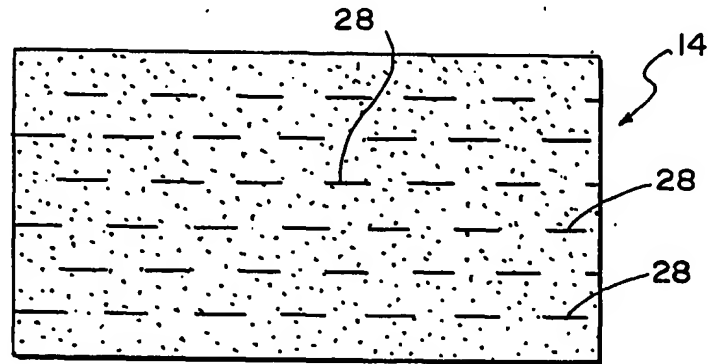
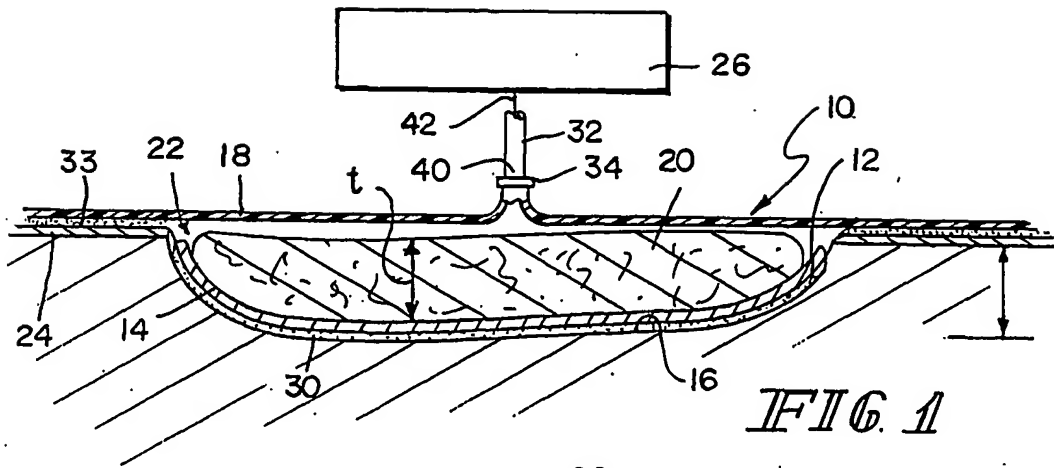
35. The method of claim 27 wherein the vacuum is generated for a sufficient period of time to begin integration of the first collagen matrix into the wound surface, and further comprising the step of placing a second collagen matrix
15 over the location of the first collagen matrix.

36. A kit for promoting wound healing comprising:
a submucosa layer for contacting the wound,
a porous pad, and
a cover for creating a seal around the wound and configured for
20 communication with a vacuum source.

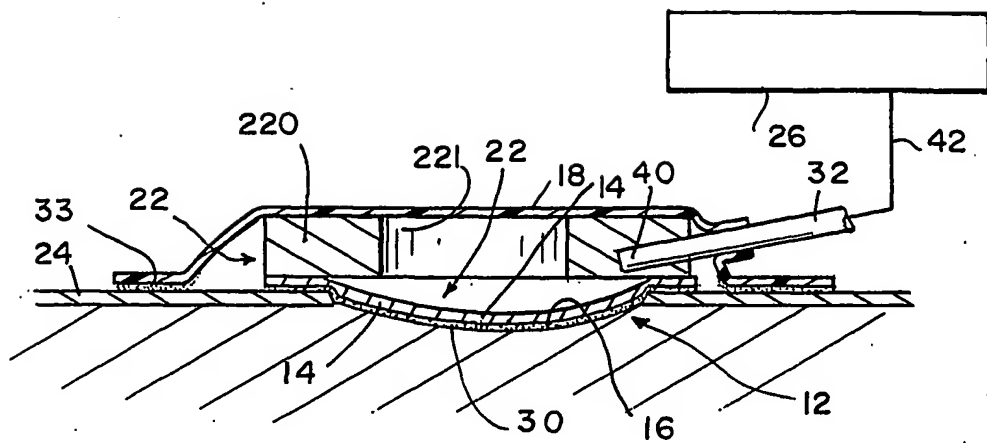
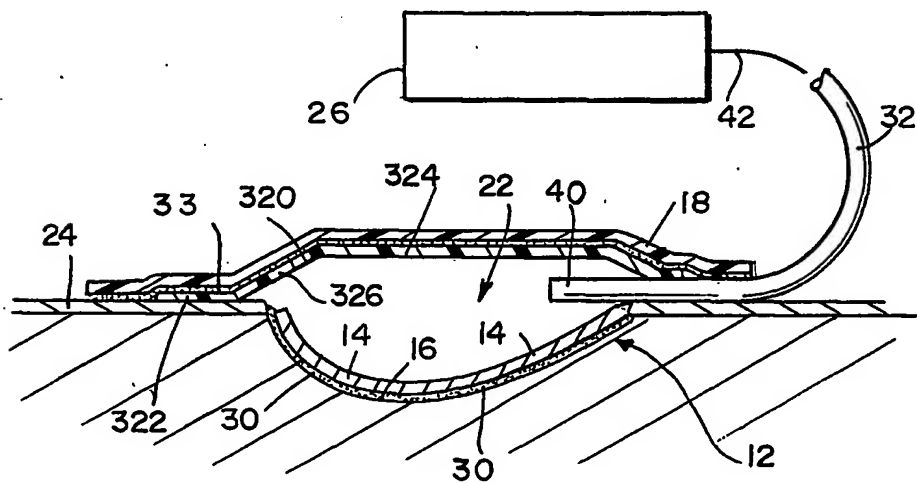
37. The kit of claim 36, further comprising a vacuum tube.

38. The kit of claim 37 wherein the submucosa layer is SIS.

1 / 2



2/2

*FIG. 4**FIG. 5*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/15611

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 5/00

US CL :602/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 602/48

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST

search terms: bandage, dressing, collagen matrix, small intestinal submucosa, collagen, vacuum

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,962,427 A (GOLDSTEIN et al.) 05 October 1999, see the entire document.	1-38
A	US 5942,496 A (Bonadio et al.) 24 August 1999, see the entire document.	1-38



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"G" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

11 JULY 2001

Date of mailing of the international search report

05 SEP 2001

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

KIM MARIE LEWIS

Telephone No. (703) 308-1191